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DATE: July 22, 2002

TO: U.S. Patent Office; Art Unit 1744

ATTENTION: Examiner M. CHORBAJI

FACSIMILE NO.: (703) 305-7719

FROM: Thomas E. Kocovsky, Jr.

RE: US Ser. No. 09/314,497; Filed 05/19/1999

Total number of pages (including this cover sheet): 14

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Comments:

14 pp : 1 pp fax cover sheet
2 pp - Amendment Transmittal Letter(s)
11 pp - Request for Reconsideration

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AMENDMENT TRANSMITTAL LETTER

Attorney Docket No. MED 2 1012

Serial No.: 09/314,497	Filing Date: May 19, 1999	Examiner: M. CHORBAJI
Group Art Unit: 1744 Confirmation: 5279	Invention: **FLOW THROUGH CHEMICAL INDICATOR FOR MEASUREMENT OF ACTIVE BIOCIDAL AGENTS**	

To the Assistant Commissioner For Patents:

Transmitted herewith is an **REQUEST FOR RECONSIDERATION** in the above-identified application. The fee has been calculated as shown below.

CLAIMS AS AMENDED						
	Claims remaining after amendment		Highest Number Previously Paid For	No. of Extra Claims Present	Rate	Additional Rate
Total Claims	23	Minus	23	-	$18	$ 0.00
Indep. Claims	4	Minus	4	-	$84	$ 0.00

_____ A check in the amount of $ _____ for the additional claims fee due is enclosed.

__X__ Please charge any additional fees or credit overpayment to Deposit Account No. 06-0308. A duplicate copy of this sheet is enclosed.

__X__ Applicants hereby request any additional extensions of time that may be necessary and authorize the extension of time fees to be charged to Deposit Account No. 06-0308.

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Respectfully submitted,

FAY, SHARPE, FAGAN,
MINNICH & MCKEE, LLP

Date: 22 July 2002

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CERTIFICATE OF FAXING

I hereby certify that these **AMENDMENT TRANSMITTAL LETTERS (x2); and REQUEST FOR RECONSIDERATION** in connection with U.S. Patent Application Serial No. 09/314,497 are being transmitted by telefacsimile to the U.S. Patent and Trademark Office, Attn: Examiner M. CHORBAJI, Art Unit 1744, at Telefacsimile No. (703) 305-7719 on this 22 day of July, 2002.

By: Hilary McNulty

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: B. SCHINDLY, et al.	)	Examiner: M. CHORBAJI
Serial No.: 09/314,497	)	Art Unit: 1744
Filed: May 19, 1999	)	Conf. No: 5279
For: FLOW THROUGH CHEMICAL INDICATOR FOR MEASUREMENT OF ACTIVE BIOCIDAL AGENTS	)	
Date of Last Office Action: May 22, 2002	)	
Attorney Docket No.: MED 2 1012	)	Cleveland, OH 44114 July 22, 2002

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REQUEST FOR RECONSIDERATION

Assistant Commissioner
For Patents
Washington, D.C. 20231

Dear Sir:

This amendment is responsive the Office Action of May 22, 2002. Reconsideration and allowance of all claims is requested.

The Office Action

All claims stand rejected under 35 U.S.C. § 103 as being unpatentable over Minerovic in view of Ignacio. Neither of these patents address the problem addressed by the present application, much less propose the presently claimed solution to it.

The References of Record

Minerovic illustrates the acknowledged prior art which is discussed starting on page 2, line 3 of the present application and continues to page 3, line 23.

Looking to the sterilizer of FIGURE 1 of Minerovic, by way of example, a unit dose of sterilant concentrate contained in a cup or package C is inserted into a well 16. As it is inserted into the well, a

projection 40 (FIGURE 2) opens a bottom closure 58 of the cup. Once the cup is inserted, only the top surface 94 of the cup is visible.

Once the cup is inserted, it is difficult to tell whether the cup is a new cup full of sterilant concentrate ready for the next cycle, or whether it is the old cup from the last cycle that has not yet been removed. If the cup is empty, left over from the last cycle, when an operator arrives to load an instrument to be sterilized, the cycle will be run, but sterilization will not be achieved. On the other hand, if the cup is full, lifting the cup will deposit the powdered reagents into the well 16 with some of the reagents possibly hanging up momentarily in the cup and being spilled in the tray 12 or on surrounding surface areas. If the operator goes to replace the cup, the deposited powdered reagent tends to prevent the cup from seating properly. Moreover, the loss of some of the powdered reagent outside of the sterilizer raises questions concerning the validity of the next sterilization cycle. There is a need for a quick and reliable way to determine whether the cup C in the well 16 is a new or a used cup.

Another problem resides in the volatile nature of the powdered reagents that form the strong oxidants. These chemicals have a limited shelf life when treated properly. The shelf life can be shortened when the cups are not treated properly. For example, extremely high temperatures during shipment, improper storage conditions, storing for longer than the prescribed shelf life, and the like can result in a new but mistreated cup failing to deliver the minimum acceptable concentrations of sterilant.

Ignacio is illustrative of the acknowledged prior art chemical indicators of the type discussed at page 4, lines 24-35 of the present application. As is known in the art, the "gold standard" of sterilization of validation is the use of a biological indicator or BI.

The BI is typically a strip of blotter paper impregnated with spores which are most resistant to the type of sterilization being performed. The piece of blotting paper is placed in the sterilization chamber in such a manner that it will be subject to the exact same (or worst case) sterilization conditions as the items being sterilized. After the cycle, the biological indicator is immersed in a culture medium and incubated for several days. If the spores do not grow, sterilization is deemed to have occurred. Of course, waiting several days for a determination of whether or not a sterilization cycle was successful is not always convenient.

Chemical indicators, such as the one illustrated in Ignacio, again include a substrate 50, such as blotting paper, which is treated with a monitor composition 51 that changes color in response to contact with the sterilant. More specifically, the color change is keyed to a concentration and time of exposure. Ignacio chooses to laminate one side 52 of the blotting paper with an impermeable film which is bonded to a permeable layer 40. A transparent, impermeable top 30 is bonded to the permeable layer to create a housing 20 which provides a vapor headspace 60. In this manner, sterilant vapor can penetrate the porous layer 40, find its way into the headspace 60, and contact the opposite side of the substrate 50.

As Ignacio explains, the chemical indicator is used to monitor the conditions to which the sterilized items are exposed. (Column 7, lines 25-29). It should be noted that Ignacio is concerned with monitoring the conditions of the sterilization process, not what is going on in other areas of the system.

To this end, Ignacio at column 9, lines 54-65 lists various conventional ways in which chemical indicators are used. First, Ignacio suggests that the blotting paper type substrate can be adhered directly to the item to be sterilized, which of course, assures that

it subject to the same exposure conditions as the item (but could trap and protect microorganisms underneath the indicator strip). In other instances, the item to be sterilized is packaged. Traditionally, items to be sterilized were wrapped in gauze, which allows steam to penetrate but not microorganisms. More recently, the gauze wrapping has been substantially superseded by the use of TYVEC™ envelopes or wraps. Various other packages which permit the sterilant to permeate, but not germs, might also be utilized. If such packaging is used, Ignacio suggests that the indicator strip can be attached to the package. While it would be preferably to place the indicator strip inside the package with the item, opening the package to check the indicator strip would expose the sterilized item to ambient microbes, destroying its sterile state. To check the conditions inside the package, Ignacio reminds us of the prior art technique of placing the chemical indicator inside the same type of package as the items being sterilized and placing that package, along with the items, in the sterilizer. After the sterilization cycle, the chemical indicator's sterilization package is opened and the indicator strip examined to provide and indication whether the appropriate exposure conditions were attained inside of the packages in the sterilization chamber.

One of the drawbacks to chemical indicators is that they are placed in the sterilization chamber manually. An operator must adhere adhesive indicators to the items. Similarly, an operator must place non-adhesive color indicator strips or prepackaged strips at various places around the sterilization chamber. Moreover, the operator must remove the indicator strips at the end of the cycle. If the indicator strips are left in the sterilizer from one cycle to the next, they can give the operator of the next cycle an erroneous indication that the next sterilization cycle was successful. Both placing indicator strips in the sterilization chamber around the

articles and removing them after the sterilization process is complete is a nuisance which busy operators, at times, fail to do in spite of the standard operating procedures.

Another difficulty with indicator strips placed in the sterilization chamber of a liquid sterilization system is that the flowing liquids exert sufficient force to move the chemical indicators around. In one cycle, a chemical indicator can be washed into a location that is not readily apparent to the operator and which is not a location in which chemical indicators are regularly placed. In the next cycle, the used indicator can be washed back into a more readily observable place.

The present application describes a simple construction which solves both the problem of quickly advising the attendant whether the cup C in the well 16 is new or used and the problem of operator error or laziness.

Minerovic makes no suggestions regarding how to determine whether the cup C is new or used. Ignacio does not discuss the location of the sterilant source, much less the use of a single dose sterilant source, much less any technique for determining whether or not a single dose sterilant supply is new or used.

The Examiner suggests that Ignacio would motivate one to adhere its indicator to the porous surface 72 of the Minerovic patent. The applicants disagree. First, placing the indicator on the surface 72 of Minerovic would place the indicator in a location where it cannot be seen by the operator, rendering it inoperative for its intended purpose. Placing the Ignacio indicator on surface 72 would not serve to provide an indicator to the attendant whether the cup in the well 16 is new or used.

Because Ignacio does not even address the issue of how to tell whether a unit dose sterilant source is new or used, it is submitted that Ignacio does not resolve this problem.

Ignacio does not address the problem of operator inattentiveness. In the present application, the indicator tells an inattentive operator instantly whether the unit dose sterilant cup is new or used. It also provides a check that a suitable supply of sterilant was generated during a just completed sterilization cycle. The indicator 44 described in the present application, unlike Ignacio, does not tell the attendant that the items have been exposed to sterilizing exposure conditions. Rather, the indicator 44 in the present application tells the operator that sterilant has been generated at the sterilant source to preselected quantities or concentrations. It does not tell the operator what the exposure conditions which the items in the sterilization chamber experienced. To determine whether the items in the sterilization chamber were exposed to the appropriate exposure conditions to achieve sterilization, one can use the chemical indicators of Ignacio, appropriately placed in the sterilization chamber. Ignacio tells whether exposure conditions for sterilization were achieved; whereas, the present indicator advises the operator of a catastrophic failure in the generation of sterilant which prevents sterilization.

The Examiner makes two assertions in the Final Rejection which the applicants traverse. First, the Examiner asserts that it is routine experimentation to place the indicator as close or as far from the item to be sterilized. To the contrary, it is the conventional wisdom in the art that the indicator must be placed in a position where it experiences as close to the identical exposure conditions as the items being sterilized. Second, the Examiner asserts that the claims of this application do not mention placing the monitor on the sterilant source. Quite to the contrary, at least some of the claims call for placing the indicator on the package which holds the composition which forms the antimicrobial or sterilant solution, i.e., the source.